NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

NOVARTIS AG and NOVARTIS PHARMACEUTICALS CORP., Plaintiffs, v. NOVADOZ PHARMACEUTICALS LLC *et al.*, Defendants.	No. 25cv849 (EP) (JRA) **OPINION**

PADIN, District Judge.

This matter comes before the Court by way of Plaintiffs Novartis AG and Novartis Pharmaceuticals Corporation's (together, "Novartis") motion for a preliminary injunction against Defendants MSN Laboratories Private Limited, MSN Pharmaceuticals Inc., and Novadoz Pharmaceuticals LLC (collectively, "MSN") for alleged infringement of Novartis's trademark, trade dress, and state rights. D.E. 4 ("PI Motion" or "PI Mot."). Novartis also moves for an injunction pending appeal. D.E. 54. The Court decides the Motion without oral argument. *See* Fed. R. Civ. P. 78(b); L. Civ. R. 78. l(b).

Upon *sua sponte* reconsideration of this Court's prior Opinion and Order entered on March 17, 2025, D.E. 33, the Court will reverse its prior ruling with respect to trade dress infringement and, accordingly, for the reasons set forth below, will **DENY** Novartis's Motion for a Preliminary Injunction and **DENY** Novartis's Motion for an Injunction Pending Appeal.

I. BACKGROUND

Entresto[1] is an FDA-approved heart failure prescription medication that delivers a combination of two drugs: sacubitril and valsartan. Since its launch in 2015, it has been the most popular heart failure branded medication and has successfully helped over 2.5 million patients avoid death and hospitalization. D.E. 1 ("Compl.") ¶¶ 3, 52-53. Entresto is available in three doses that each vary in configuration. The "Low Starting Dose" is a violet white oval tablet that measures 13.1 mm x 5.2 mm and contains a 24/26 mg dose. *Id.* ¶¶ 15, 59. The "Recommended Starting Dose" is a pale yellow oval tablet that measures 13.1 mm x. 5.2. mm and contains a 49/51 mg dose. *Id.* The "Target Dose" is a light pink oval tablet that measures 15.1 mm x 6.0 mm and contains a 97/103 mg dose. *Id.* Each tablet is marked with "NVR." D.E. 4-4 ("Valazza Decl.") ¶ 15.

Upon the expiration of Novartis's patent-related exclusivity on July 16, 2025, MSN intends to market a generic version of Entresto under MSN's "Novadoz" name. Compl. ¶¶ 6-7, 89; D.E. 49. As mandated by law, MSN's generic will contain the same active ingredients as Entresto, be available in the same dosage forms, and will deliver the same doses. D.E. 13-7 ("Nithiyanadam Decl.") ¶¶ 3-5. However, its dimensions, coloring, and markings will differ slightly. The proposed dimensions for MSN's generic measure at 10 x 4 mm, 13 x 5.10 mm, and 15 x 5.9 mm respectively for its 24/26 mg tablet, 49/51 mg tablet, and 97/103 mg tablet. *Id.* ¶ 6. The proposed tablets are marked with an "M", slightly smaller, and similar in coloring, though not identical to Entresto.

[1] Novartis refers to Entresto as "ENTRESTO®" in its briefing. *See generally* PI Mot., D.E. 17 ("PI Reply"). The Court refers to Novartis's drug as "Entresto" here.

PARAMETERS	REFERENCE LISTED DRUG	PROPOSED DRUG PRODUCT
Strengths	24 mg/ 26 mg, 49 mg / 51 mg and 97 mg/ 103 mg	24 mg/ 26 mg, 49 mg / 51 mg and 97 mg/ 103 mg
Configuration		
24 mg/ 26 mg, 49 mg / 51 mg and 97 mg/ 103 mg	Bottle of 60's and 180's	Bottle of 60's and 180's
24 mg/ 26 mg		
49 mg/ 51 mg		
97 mg/ 103 mg		
Dimensions		
24 mg/ 26 mg	13.35 x 5.33	10.00 X 4.00 mm
49 mg/ 51 mg	13.25 x 5.30	13.00 X 5.10 mm
97 mg/ 103 mg	15.34 x 6.12	15.00 X 5.90 mm
Active Ingredient	Sacubitril and Valsartan	Sacubitril and Valsartan

Id.

II. PROCEDURAL HISTORY

On January 31, 2025, Novartis moved for a preliminary injunction seeking to enjoin the market entry of MSN's generic.[2] PI Mot. MSN opposed, D.E. 13 ("PI Opp'n"), and Novartis replied, PI Reply. On March 17, 2025, this Court concluded that although Novartis had not shown that it was likely to succeed on the merits of its trademark infringement and state law claims, it was likely to succeed on its trade dress infringement claim. D.E. 32 ("PI Opinion") at 18, 21. After additionally concluding that other preliminary injunction factors favored Novartis, this Court granted a preliminary injunction enjoining MSN from infringing Novartis's trade dress rights. *Id.* at 17-18; D.E. 33 ("PI Order").

On March 24, 2025, MSN appealed the grant of a preliminary injunction to the Third Circuit. D.E. 35. On April 4, 2025, this Court issued a text order advising the parties that it was

[2] Novartis also contemporaneously moved for a temporary restraining order, which this Court denied. D.E. 7.

contemplating *sua sponte* reconsideration of the PI Opinion and it provided the parties an opportunity to submit further briefing. D.E. 43. Both parties responded. D.Es. 45-46. MSN's appeal to the Third Circuit, however, had divested this Court of jurisdiction and rendered this Court unable to reconsider the PI Opinion. *See* D.E. 51 at 4 n.1 (citing *Venen v. Sweet*, 758 F.2d 117, 120 (3d Cir. 1985)).

On May 22, 2025, this Court did, however, stay its injunction pending MSN's appeal. D.Es. 51 ("Stay Opinion"), 52. The Court concluded that MSN was likely to succeed on the merits of its appeal because the Court had improperly applied governing law regarding Novartis's trade dress infringement claim. Stay Opinion at 4-5 & n.2 (citing *Thompson Reuters Enter. Ctr. GmbH v. Ross Intel. Inc.*, No. 20-613, 2025 WL 458520, at *1 (D. Del. Feb. 11, 2025)). In light of the procedural posture and this Court's Stay Opinion, the Third Circuit issued a limited remand to permit this Court's reconsideration of its PI Opinion. *Novartis AG v. Novadoz Pharms. LLC*, No. 25-1550, D.E. 28 (3d Cir. 2025). The Court now has jurisdiction and issues its reconsidered opinion with respect to Novartis's trade dress claim.[3] Novartis also seeks an injunction pending appeal of this Court's reconsidered opinion. D.E. 54.

[3] Novartis also brought claims for trademark infringement, false designation of origin, and unfair competition. Compl. ¶¶ 128-205. The Court denied Novartis's request for a preliminary injunction with respect to those claims after concluding it had not demonstrated likelihood of confusion, a prerequisite for each claim. *See Checkpoint Sys., Inc. v. Check Point Software Tech., Inc.*, 269 F.3d 270, 279 & n.5 (3d Cir. 2001) (explaining that trademark infringement and unfair competition share the same elements and consequently, the same analysis); *Parks LLC v. Tyson Foods, Inc.*, 863 F.3d 220, 226 (3d Cir. 2017) (explaining that a false designation of origin claim in turn relies upon "proving the existence of a protectable mark" under the Lanham Act) (quoting *E.T. Browne Drug Co. v. Cococare Prod., Inc.*, 538 F.3d 185, 191 (3d Cir. 2008)). The Court reconsiders its PI Opinion only with respect to the preliminary injunction it granted to prevent trade dress infringement. The Court does not disturb its other findings.

III. RECONSIDERATION

Although a district court "should be loathe to do so," it has discretion to revisit prior decisions of its own and should do so "where a prior ruling . . . might lead to an unjust result." *In re Pharmacy Benefit Managers Antitrust Litig.*, 582 F.3d 432, 439 (3d Cir. 2009) (quoting *Messenger v. Anderson*, 225 U.S. 436, 32 (1912)). A district court that decides to change an earlier ruling—as this Court will do here—must "state [its] reasons on the record" and "take appropriate steps so that the parties are not prejudiced by reliance on the prior ruling." *Id.* (quoting *Swietlowich v. County of Bucks*, 610 F.2d 1157, 1164 (3d Cir. 1979)).

Novartis asks this Court to enjoin the entry of a would-be generic competitor. This Court granted that extraordinary relief and enjoined MSN's market entry and, by extension, the potential market entry of other "strikingly similar" generics. PI Opinion at 3, 21; *see also* Nithiyandam Decl. ¶ 18 (explaining that "the appearance of every other FDA-approved Entresto generic drug for which that information is publicly available" mimics the appearance of Entresto). The grant of that extraordinary relief was error. The Court imposed too high a standard in its assessment of non-functionality, did not take the nature of Novartis's product configuration trade dress claim into account for secondary meaning or likelihood of confusion, and did not apply the correct legal framework when evaluating irreparable harm. While there may be circumstances where a generic competitor should be excluded from the market because of trade dress infringement, the Court is satisfied that this case does not present such circumstances. As Novartis explains, the life-saving drug at issue here may impact millions of patients and is responsible for generating billions in

sales.[4] D.E. 4-3 ("Miller Decl.") ¶¶ 20, 25-26. Accordingly, the Court concludes that reconsideration of its prior trade dress ruling is warranted here to prevent injustice.

IV. LEGAL STANDARD

A preliminary injunction is "'an extraordinary remedy' and 'should be granted only in limited circumstances.'" *See Kos Pharms., Inc. v. Andrx Corp.*, 369 F.3d 700, 708 (3d Cir. 2004) (quoting *Am. Tel. & Tel. Co. v. Winback & Conserve Program, Inc.*, 42 F.3d 1421, 1427 (3d Cir. 1994)). Such extraordinary relief should be granted only if a party shows:

> (1) a likelihood of success on the merits; (2) that it will suffer irreparable harm if the injunction is denied; (3) that granting preliminary relief will not result in even greater harm to the nonmoving party; and (4) that the public interest favors such relief.

Id. (citing *Allegheny Energy, Inc. v. DQE, Inc.*, 171 F.3d 153, 158 (3d Cir. 1999)). Although the first two factors are particularly critical, *Reilly v. City of Harrisburg*, 858 F.3d 173, 176 (3d Cir. 2017), a party's "failure to establish any element in its favor renders a preliminary injunction inappropriate," *Conestoga Wood Specialties Corp. v. Secretary of U.S. Department of Health and Human Services.*, No. 13-1144, 2013 WL 1277419, at *1 (3d Cir. Feb. 8, 2013) (internal quotations omitted). The same standard also applies to injunctions pending appeal under Fed. R. Civ. P. 62(d). *Newborn Bros. Co., Inc. v. Albion Engineering Co.*, No. 12-02999, 2024 WL 2720461, at *2 (D.N.J. May 28, 2024) (citing *Conestoga Wood*, 2013 WL 1277419, at *1).

[4] Entresto is an important drug for millions of patients. *See* D.E. 4-1 at 20 ("ENTRESTO® is a blockbuster drug taken twice a day, indefinitely, by over 2.5 million patients."); *see also* D.E. 42 at 2 (explaining that Entresto "is the number one branded heart failure treatment prescribed by physicians" and is a "life changing heart failure medication"); D.E. 13-40 ("Clark Decl.") ¶ 31 ("Entresto contributed approximately $3 billion (or 17%) of Novartis's $ 18.1 billion in U.S. sales."), ¶ 37 (Entresto is "the leading branded therapy for heart failure prescribed by cardiologists and is recommended for first-line treatment of CHF in guidelines from the American Heart Association, American College of Cardiology, and the Heart Failure Society of America.").

V. ANALYSIS

A. Likelihood of Success

Novartis seeks to enjoin MSN from infringing its trade dress, in violation of the Lanham Act § 1125(a). To succeed on a trade dress infringement claim, Novartis must prove:

> (1) the allegedly infringing design is nonfunctional; (2) the design is inherently distinctive or has acquired secondary meaning; and (3) consumers are likely to confuse the source of the plaintiff's product with that of the defendant's product.

McNeil Nutritionals, LLC v. Heartland Sweeteners, LLC, 511 F.3d 350, 357 (3d Cir. 2007). For the reasons explained below, the Court finds that Novartis is unlikely to succeed on the merits of its trade dress infringement claim because the trade dresses are functional, have not acquired secondary meaning, and consumers are not likely to confuse the source of Novartis's and MSN's tablets based upon trade dress.

1. Functionality

Trade dress is a type of trademark. It serves to protect distinctive choices "like size, shape, and color" that are responsible for "the overall look of a product." *PIM Brands, Inc. v. Haribo of Am. Inc.*, 81 F.4th 317, 321 (3d Cir. 2023) (quoting *Ezaki Glico Kabushiki Kaisha v. Lotte Int'l Am. Corp.*, 986 F.3d 250, 255 (3d Cir. 2021)). Trade dress does not, however, protect functional features. *Id.* Functionality falls within the purview of patent law, where the law works to foster innovation. *Shire US Inc. v. Barr Lab'ys, Inc.*, 329 F.3d 348, 353 (3d Cir. 2003). The Lanham Act seeks to accomplish somewhat different goals. The Lanham Act "protects the manufacturer (and the consumer) from the copying of those features that signify a product's source (and quality) and encourages competition by preventing one manufacturer from acquiring a monopoly by attempting

to trademark those features of a design [useful] to a successful product of that type."[5] *Id.* (quoting *Standard Terry Mills, Inc. v. Shen Mfg. Co.*, 803 F.2d 778, 780-81 (3d Cir. 1996)).

The standard for finding functionality is supposed to be low. *PIM Brands*, 81 F.4th at 321. "A design is functional if it is useful for *anything* beyond branding." *Id.* (emphasis added). That includes features which "would put competitors at a significant non-reputation-related disadvantage." *Qualitex Co. v. Jacobson Prods. Co.*, 514 U.S. 159, 165 (1995). Indeed, the Supreme Court in *TrafFix Devices, Inc. v. Marketing Displays, Inc.*, cautioned courts against the "misuse or overextension of trade dress." 523 U.S. 23, 29 (2001) (citing *Wal-Mart Stores, Inc. v. Samara Brothers, Inc.*, 529 U.S. 205, 120 (2000)); *see also Shire*, 329 F.3d at 359 n.22 (explaining that "in many instances there is no prohibition against copying goods and products") (quoting *TrafFix*, 532 U.S. at 29).

Against this backdrop, the Court notes that prescription drugs raise at least two unique issues for trade dress law. *First*, modern generic drugs like MSN's must meet stringent FDA standards, allaying trade dress policy concerns that seek to protect manufacturers and consumers from relying on "the overall look of a product" to indicate quality. *See Shire*, 329 F.3d at 355 n.14; *see also id.* at 356 n.17.[6] Indeed, "drug color cases have more to do with public health policy regarding generic drug substitution than with trademark law." *Id.* (quoting *Qualitex*, 514 U.S. at

[5] "Functional designs need not be *essential*, just useful." *Ezaki Glico*, 986 F.3d at 256 (emphasis added).

[6] "A generic medicine is required to be the same as a brand-name medicine in dosage, safety, effectiveness, strength, stability, and quality, as well as in the way it is taken. Generic medicines also have the same risks and benefits as their brand-name counterparts." Clark Decl. at ¶ 26 (quoting U.S. FOOD & DRUG. ADMIN., GENERIC DRUG FACTS, FDA (2021), available at https://www.fda.gov/drugs/generic-drugs/generic-drug-facts).

169). This alone distinguishes pre-Hatch-Waxman trade dress cases from those that post-date it.[7] *See id.* at 356 n.17 (collecting cases).

Second, for many patients, the overall look of a drug can "come to represent to large numbers of those taking [the drug] not its source but its ingredients and their effects." *Id.* at 358 n.20; *see also Inwood Lab'ys, Inc. v. Ives Lab'ys, Inc.*, 456 U.S. 844, 853 (1982). This association—tied to the drug product's overall appearance—can confer functionality for patient populations who rely on appearance to identify their medication and would put competitors at a significant disadvantage if they cannot replicate or approximate those features. *See Qualitex*, 514 U.S. at 170 (stating in dicta that color serves "a significant nontrademark function" if it serves "to distinguish a heart pill from a digestive medicine"). Even the FDA prefers that generics look like their reference drug counterparts. *See* U.S. FOOD & DRUG ADMIN., SIZE, SHAPE, AND OTHER PHYSICAL ATTRIBUTES OF GENERIC TABLETS AND CAPSULES: GUIDANCE FOR INDUSTRY (2022), available at https://www.fda.gov/media/161902/download (hereinafter "FDA Physical Attribute Guidance") at 1 (expressing "concer[n] that differences in physical characteristics (e.g., size and shape of the tablet or capsule) may affect patient compliance and acceptability of medication regimens or could lead to medication errors.").

"In a civil action for trade dress infringement under this chapter for trade dress nor registered on the principal register, the person who asserts trade dress protection has the burden of proving that the matter sought to be protected is not functional." 15 U.S.C. § 1125(a)(3). As

[7] The Hatch-Waxman Act was passed in 1984, which caused an explosive change in the drug marketplace. Before Hatch-Waxman, less than twenty percent of total prescriptions dispensed were generic drugs. H.R. Rep. No. 98-857, pt. 1, at 28 (1984); 130 Cong. Rec. 24,430 (1984) (statement of Rep. Waxman). Today, nine out of ten prescriptions are filled with generic drugs. U.S. FOOD & DRUG ADMIN., GENERIC DRUGS (2021), available at https://www.fda.gov/drugs/buying-using-medicine-safely/generic-drugs.

Novartis has no registered trade dress, it is Novartis's burden to prove non-functionality. *Id.* For the reasons explained below, the Court concludes that Novartis has not shown that the Entresto trade dresses are nonfunctional.

a. Arbitrary selection is not dispositive

The Supreme Court explained in *Inwood Laboratories, Inc. v. Ives Laboratories, Inc.*, that the colors of a medication—although "arbitrarily selected"—may nonetheless be

> functional to patients as well as doctors and hospitals; many elderly patients associate color with therapeutic effect; some patients comingle medications in a container and rely on color to differentiate one from another; colors are of some, if limited, help in identifying drugs in emergency situations; and use of the same color for brand name drugs and their generic equivalents helps avoid confusion on the part of those responsible for dispensing drugs.

456 U.S. 844, 846-47, 853 (1982). *Inwood Laboratories* thus indicates that utility for healthcare providers, as well as patients, is relevant to functionality. Following the Supreme Court's reasoning, it is the Court's view that although "there may have been no functional reason [for Novartis] to have chosen violet white, pale yellow, and light pink tablets in the first instance, the tablet's appearances, once chosen can 'come to represent to large numbers of those taking [the drugs] not its source but its ingredients and effects.'" Stay Opinion at 9 (quoting *Shire*, 329 F.3d at 358 n.20). Indeed, the Supreme Court has cautioned that "product design almost invariably serves purposes other than source identification." *Wal-Mart*, 529 U.S. at 213. Therefore, evidence that the colors of Entresto were "arbitrary design choices," PI Mot at 17, selected for reasons "unrelated to function or efficacy" is not dispositive, Valazza Decl. ¶ 17.

b. Visual cues have functional utility

Entresto patients raise the same functionality concerns as those discussed by the Supreme Court in *Inwood Laboratories* and the Third Circuit in *Shire*. For example, the majority of chronic heart failure ("CHF") patients take five or more medications and may rely on color and overall

appearance to distinguish among their various medications. Clark Decl. ¶ 75; D.E. 13-46 ("Shimer Decl.") ¶ 48; D.E. 4-10 ("Robbins Decl.") ¶ 16. And because CHF is a chronic condition, patients typically take their CHF medication "into seeming perpetuity" and come to expect visual continuity, even after switching to a generic. PI Opinion at 9; *see also* Robbins Decl. ¶¶ 13-15; Miller Decl. at ¶¶ 18-20; Clark Decl. ¶¶ 20, 53; Shimer Decl. ¶ 47.

These visual cues are important for therapeutic adherence. Generics purposefully and routinely mimic the overall appearance of reference drugs to avoid disrupting visual continuity in a patient's drug regimen.[8] Clark Decl. ¶ 21; Shimer Decl. ¶ 45. The effect is not insubstantial. *Shire*, 329 F.3d at 358 n.21 (noting that "'the constancy of color and shape may be psychologically reassuring and therefore as medically beneficial as the drug itself'") (quoting *Inwood Lab'ys*, 456 U.S. at 862 n.3 (White, J., concurring)); *see also id.* at 358 (affirming district court's factual finding that "similarity in tablet appearance enhances patient safety by promoting psychological acceptance").

The Court does not find Novartis's arguments to the contrary persuasive. *First*, Novartis relies on pre-*Shire* cases finding that the overall appearance of prescription drugs was not functional. PI Mot. at 17. But as this Court explained above, these pre-Hatch-Waxman cases are

[8] This increasingly common industry practice also distinguishes the pre-Hatch-Waxman cases cited by Novartis. *See SK & F, Co. v. Premo Pharm. Lab'ys, Inc.*, 625 F.2d 1055, 1064 (3d Cir. 1980) (finding that a drug's color conferred no functionality in part because there was "ample evidence that neither the capsule form nor the color combination reflects any industry practice . . . ."). Here, however, there is evidence demonstrating that generics routinely—although not always—mirror or approximate the overall appearance of the reference drug. Nithiyanadam Decl. ¶ 6; *see also* Clark Dec. ¶ 102 (comparing physical features between generic drugs and reference drugs). Indeed, MSN identified four other Entresto generics that also use small ovaloid off white, light or pale yellow, and light pink tablets for their three strengths. D.E. 13-8; *see also* PI Opp'n at 8 n.4 ("[S]o far as can be gleaned from publicly available information, every other ANDA applicant for a generic Entresto product . . . also use[s] a similar light purple, pale yellow, and light pink color scheme, and also use[s] an ovaloid shape.").

distinguishable. *See supra* section V.A.1. Novartis particularly relies on *Ciba-Geigy Corp. v. Bolar Pharmaceuticals, Co., Inc.*, but the Third Circuit there did not address the functionality arguments raised here, and which were later credited by *Shire*. *Compare Ciba-Geigy*, 747 F.2d 844, 850-51 (3d Cir. 1984) (affirming non-functionality because Bolar's functionality arguments "were premised primarily on the assumption that physicians and pharmacists would prescribe a drug based on its appearance only"), *with Shire*, 329 F.3d at 355 (affirming functionality because similarity in appearance "enhances patient safety and compliance with the medically prescribed dosing regimen").

Second, Novartis relies on its expert declarations, but their statements are not compelling. Dr. Robbins opines that the FDA's recommendations regarding a generic drug's mirroring of a reference drug's physical attributes do not include specific guidance regarding color choices and that the FDA's recommendations stem from "ease of swallowing" concerns. D.E. 17-2 ("Robbins Rebuttal Decl.") ¶¶ 10-11 (internal quotations omitted) (citing FDA Physical Attribute Guidance at 4). But the FDA's recommendations are not limited to "ease of swallowing concerns." The FDA also recommends considering "patient compliance and acceptability of medication regimens"—a function recognized by *Shire*. FDA Physical Attribute Guidance at 1, 4; *Shire*, 329 F.3d at 355.

Dr. Robbins further contends that MSN's expert Dr. Shimer's reliance on the FDA's Physical Attribute Guidance is misplaced because the FDA admits that "generic medicines may look different than the brand-name drugs they duplicate" and because Dr. Shimer's own publications find that the most generic drugs differ in at least one of four physical attributes examined compared to the reference drug.[9] Robbins Rebuttal Decl. ¶¶ 11-12. But a product's

[9] Dr. Clark looked at color, shape, score, size, and imprint code. Clark Decl. ¶¶ 102-03.

appearance can be functional "even when there are alternatives." *Ezaki Glico*, 986 F.3d at 260. And Dr. Robbins himself admits that a pill's overall appearance can "serve as a reference point for patients to identify the particular medication they are prescribed." Robbins Decl. ¶ 17.

Finally, Dr. Robbins states that Dr. Clark overlooks other factors that impact patient adherence. Robbins Rebuttal Decl. ¶ 13. The Supreme Court, however, made clear that a feature need not be functional for every consumer when it found functionality in *Inwood Laboratories* based upon evidence that "*some* patients commingle medications in a container and rely on color to differentiate one from another." *Inwood Lab'ys*, 456 U.S. at 853. Nor does the law require that a feature be functional in all aspects. The functionality bar is low. It does not matter that other features may impact patient adherence. The fact that overall appearance is useful is enough. *Ezaki Glico*, 986 F.3d at 256.

Considering the full record, the appearance of Entresto is functional because elderly patients and patients with comorbidities (i.e., many of the patients who take Entresto) rely on visual cues to help identify the effects of and distinguish their heart failure medication. Stay Opinion at 9-10 (quoting PI Opinion at 9). And because those patients rely on overall appearance for visual continuity, which impacts patient adherence, generic competitors would suffer a significant disadvantage if they could not mirror those features. *Inwood Lab'ys*, 456 U.S. at 853; *see also Qualitex*, 514 U.S. at 169 ("The functionality doctrine thus protects competitors against a disadvantage . . . namely, their inability reasonably to replicate important non-reputation-related product features.").

c. Dosage coding is functional

Novartis's use of different colors and sizes across different dosages is functional as well. Patients begin on lower doses of Entresto before progressing up to different and higher dosage

strengths. D.E. 4-11 ("Nayeri Decl.") ¶ 17. Distinguishing the different dosage strengths by color and by size permits patients who are exposed to more than one dosage strength over the course of their treatment to rely on color and size to visually convey dosage information. *See* PI Mot. at 10 ("some patients progress through the various doses of Entresto, exposing them to the Trio Trade Dress over time"); *see also* Clark Decl. ¶ 48; Nithiyanandam Decl. ¶ 10; Nayeri Decl. ¶ 17. Therefore, just as the Third Circuit found in *Shire*, the Court here finds that the record supports that distinguishing between the different dosages "confers a substantial degree of clinical functionality for the patient in the titration/adjustment process." *Shire*, 329 F.3d at 354.

d. Size and shape are functional in additional ways

The size and shape of Entresto are functional too. Here, MSN again marshals compelling evidence demonstrating that the size and ovaloid shape of Entresto influence patient administrability, manufacturing costs, and transit time after ingestion. MSN's expert, Dr. Nithiyanandam points out that "hundreds if not thousands of other drug companies choose an ovaloid shape for their tablets" because ovaloid shapes are easier to swallow and more cost-effective to manufacture. Nithiyanandam Decl. ¶ 12. The FDA similarly lauds ovaloid shapes as "easier to swallow." Shimer Decl. ¶ 41 (citing FDA's Physical Attribute Guidance at 3, 5-6). The same goes for size. Smaller tablets are easier to swallow, and FDA Guidance demonstrates that tablet size affects esophageal transit time. *Id.*

Novartis does not dispute that size and shape matter. PI Mot. at 17-20; PI Reply at 3-5. Novartis instead maintains that it chose the size and shape of Entresto to distinguish it from competing products. PI Reply at 2, 3. But as explained above in section V.A.1, just because Novartis selected a particular product design to distinguish its product in the market does not compel the conclusion that the product design lacks functionality.

2. Secondary Meaning[10]

Because Novartis does not argue that the overall appearance of Entresto is inherently distinctive, the Court addresses only whether the Entresto trade dresses have acquired secondary meaning. PI Mot. at 19. A trade dress acquires secondary meaning when "in the minds of the consuming public, [it serves] to identify the *product's source* rather than the *product itself*." *Wal-Mart*, 529 U.S. at 205-06 (emphasis added).[11] The Third Circuit has identified several non-exclusive factors relevant to secondary meaning:

> (1) the extent of sales and advertising leading to buyer association; (2) length of use; (3) exclusivity of use; (4) the fact of copying; (5) customer surveys; (6) customer testimony; (7) the use of the mark in trade journals; (8) the size of the company; (9) the number of sales; (10) the number of customers; and, (11) actual confusion.

[10] MSN raises the argument that because Novartis's trade dresses are generic, it is ineligible for trade dress protection. PI Opp'n at 17. MSN points to extensive use of the trade dress features across the entire pharmaceutical industry. D.E. 13-23; Nithiyandam Decl. ¶ 12, Clark Decl. ¶¶ 83-84. Because the Court finds that the trade dresses are functional and there is no secondary meaning, it will not address MSN's genericness argument.

[11] Here, the consuming public includes both patients and healthcare providers. Although the Court considers both groups in its analysis here and for likelihood of confusion, *see infra* section V.A.3, the Court's analysis sometimes focuses on the end-user as opposed to the product selector where appropriate (and based on the parties' evidence which, at times, is limited to only one group or the other). *See Kos Pharms.*, 369 F.3d at 715 & n.12 (noting that healthcare providers and patients may both make up the market in prescription drug cases).

Parks LLC v. Tyson Foods, Inc., 863 F.3d 220, 231 (3d Cir. 2017). The Court, however, notes that because Novartis's trade dress claim "is predicated upon infringement of the trade dress of the product itself" (as opposed to the packaging of the product), this is a product configuration case. *See Duraco Prods. Inc. v. Joy Plastic Enterprises, Ltd.*, 40 F.3d 1431, 1434 & 1439 (3d Cir. 1994) (explaining that product configuration applies when "the total image of a product, including features such as size, shape, color or color combinations, texture, graphic, or even particular sales techniques" are at issue).[12]

Because "product configurations in general are not reliable as source indicators," they raise unique challenges for trademark law. *Versa Prods. Co., Inc. v. Bifold Co. (Mfg.) Ltd.*, 50 F.3d 189, 201 (3d Cir. 1995) (citing *Duraco*, 40 F.3d at 1441, 1448-49, 1451); *see Duraco*, 40 F.3d at 1440-42 (holding that "the particularity of trademarks . . . does not fit the quite different considerations applicable to product configurations"); *see also Versa*, 50 F.3d at 202 ("[T]he law of trade dress in product configurations will differ in key respects from the law of trademarks or of trade dress in product packaging . . . ."). As the Supreme Court explained in *Wal-Mart Stores*, "[i]n the case of product design . . . consumer predisposition to equate the feature with the source *does not exist*." 529 U.S. at 213 (emphasis added). "[A]lmost invariably, even the most unusual product designs—such as a cocktail shaker shaped like a penguin—is intended not to signify the source, but to render the product itself more useful or more appealing." *Id.*

[12] The law sometimes refers to the overall product's design as "product configuration" or as "product design." *Compare Duraco*, 40 F.3d 1431 (using the term "product configuration"), *Versa*, 50 F.3d 189 (using the term "product configuration"), *and Shire*, 329 F.3d 348 (using the term "product configuration" to refer to a product's appearance), *with Wal-Mart*, 529 U.S. 205 (using the term "product design" to refer to a product's appearance), *and Buzz Bees Toys, Inc. v. Swimways Corp.*, 20 F. Supp. 3d 483 (D.N.J. 2014) (using both terms).

A different approach in the product configuration context must therefore apply compared to trademark cases and product packaging cases. *See Duraco*, 40 F.3d at 1447 ("even the basic design of a light bulb is capable of identifying a particular source of a product . . . assuming that only one manufacturer produces the basic design, a fact which would be assured, of course, if the design were protected against copying"). Taking this context into account and as further discussed below, Novartis has not shown that the consuming public understands the overall appearance of Entresto to primarily identify Novartis.

a. Extent of advertising and sales

Generally, the public comes to associate a trade dress with a product's source "through extensive advertising." *Tyson Foods*, 863 F.3d at 232. A "prevalent advertising campaign" that runs for an extended period permits a district court to infer secondary meaning. *E.T. Browne Drug Co. v. Cococare Prods., Inc.*, 538 F.3d 185, 200 (3d Cir. 2008). For product configuration cases, the Court looks at the plaintiff's "advertising expenditures, measured primarily with regard to those advertisements which *highlight the supposedly distinctive identifying feature* . . . ." *Duraco*, 40 F.3d at 1452 (emphasis added). The advertising should "*direct* the consumer to those features claimed as trade dress." *Buzz Bees Toys*, 20 F. Supp. 3d at 500 (emphasis added) (quoting *Yankee Candle Co., Inc. v. Bridgewater Candle Co., LLC*, 259 F.3d 25, 44 (1st Cir. 2001)).

The evidence Novartis presented does not indicate that it ran a "prevalent advertising campaign" that "directed" consumers to the claimed trade dresses. *Astrazeneca AB v. Dr. Reddy's Laboratories, Inc.*, is instructive. 145 F. Supp. 3d 311 314 (D. Del. 2015). There, Astrazeneca "prominently" featured its distinctive color purple and invested over $250 million per year in promoting its purple brand. *Id.* Astrazeneca advertised both its Prilosec product as "the only purple pill that treats heartburn due to acid-reflux disease" and its Nexium product on a

"predominantly purple website that prominently displays Nexium capsules and AZ's trademark 'The Purple Pill.'" *Id.* Using the same distinctive color across multiple products helps consumers associate the trade dress with the brand, as opposed to just the product.

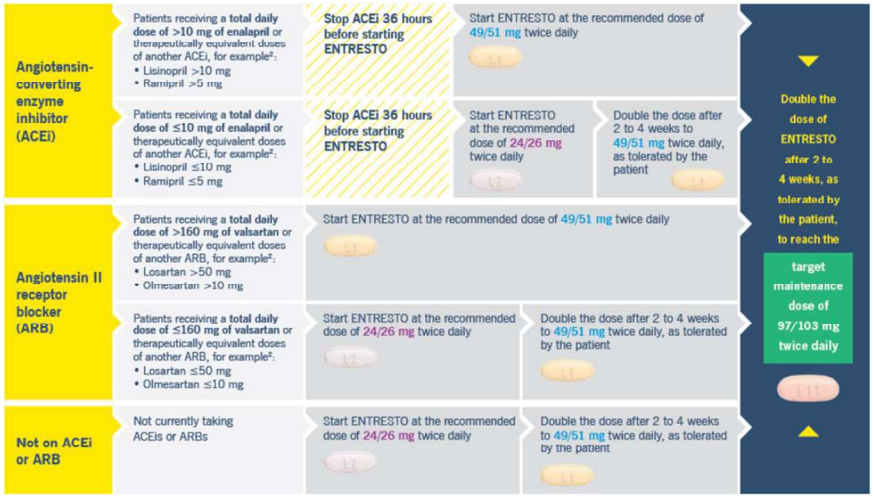
In *Duraco*, the Third Circuit explained that although "secondary meaning in a product configuration case will generally not be easy to establish," it may be easier "with respect to drugs or pills with unusual colors and/or shapes [where] a consumer may be more likely to rely on the product's configuration as a source designator." 40 F.3d at 1453. The parties here do not argue that off white, pale yellow, and light pink are "unusual" colors for drugs. Instead, MSN points to several other drugs that use similar colors, including other heart failure medications. *See, e.g.*, PI Opp'n at 17 ("[T]here are many off-white, yellow, and pink pills on the market, including heart medications.") (citing Carrero Decl. Ex. 1). Even Novartis acknowledges that some other heart medications share the same colors as Entresto. PI Mot. at 18.

Christian Louboutin shoes serve as another illustrative example. The lacquered red outsole gained secondary meaning when it became "'uniquely' associated with the Louboutin brand." *Christian Louboutin S.A. v. Yves Saint Laurent Am. Hldgs., Inc.*, 696 F.3d 206, 226-27 (2d Cir. 2012) (quoting *Qualitex*, 514 U.S. at 162). There, Louboutin invested in promoting its red outsole as "its signature in women's high fashion footwear" and the red outsole came to "'identify and distinguish' the Louboutin brand." *Id.* (quoting *Qualitex*, 514 U.S. at 163). There too, the red outsole became associated with the brand generally and not just with a specific product.

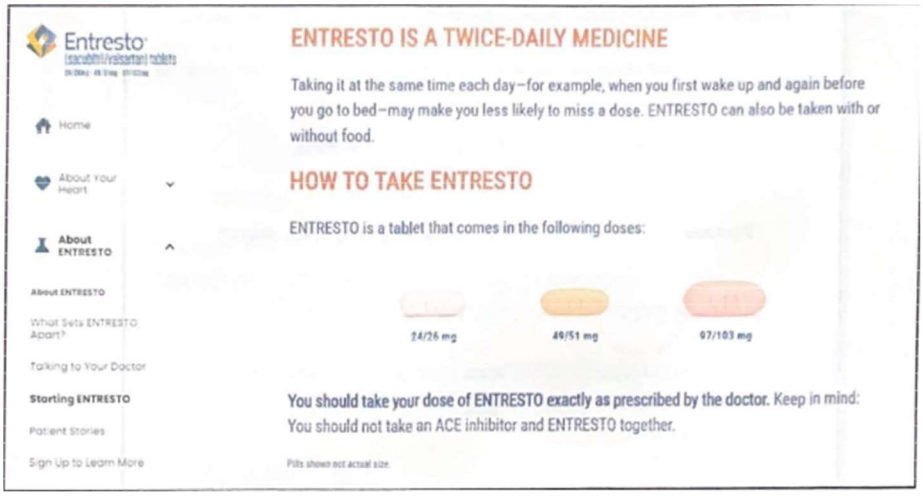
In contrast here, the evidence does not show that the trade dresses of Entresto have come to be understood as symbols of the Novartis brand. Although Novartis may have hoped to acquire secondary meaning, Novartis has not shown it achieved that goal. *See Cococare Prods.*, 538 F.3d at 199 (finding no evidence that plaintiff acquired secondary meaning despite using the mark "on

many occasions over a long period of time"). While Novartis invested about $2.1 million total in developing webpages and resources and over $200,000 printing resources for distribution to healthcare providers, Miller Decl. ¶ 44, those materials do not draw specific attention to the appearance of Entresto for consumers in a way that associates it with Novartis.

Novartis claims that it highlighted the Entresto trade dress in its advertisements, but Novartis's advertisements merely include the trade dresses alongside information that identifies what the product does, how often to take it, and what dosages are available. The advertisements do not appear to create an association between the small ovaloid violet white, pale yellow, and light pink tablets and Novartis. A few representative examples of Novartis's advertisements are included below:



Miller Decl. ¶ 37.



Miller Decl. ¶ 43.

Nor do Novartis's success in sales remedy this shortcoming. Top sales can support secondary meaning when sales increase alongside marketing. *Cococare Prods.*, 538 F.3d at 199-200. However, in the product configuration context, sales success may not be as probative. "In this respect product configuration again differs dramatically from trademark and product packaging, since the success of a particular product . . . does not readily lead to an inference of source identification and consumer interest in the source." *McNeil Nutritionals, LLC v. Heartland Sweeteners LLC*, 566 F. Supp. 2d 378, 391 (E.D. Pa. 2008) (quoting *Duraco*, 40 F.3d at 1252-53). Moreover, Novartis's expert concedes that Entresto's "lifechanging capabilities" drove its successful sales and lasting impression. Miller Decl. ¶ 30. Considering this evidence, the Court cannot infer that the appearance of Entresto has left a lasting impression in the minds of consumers connecting it to Novartis as a source or that advertising the mark drove Novartis's sales. *See Cococare Prods.*, 538 F.3d at 199 (finding that the record lacked evidence showing "what lasting impression the advertising [of the mark] left in the mind of consumers or what portion of Browne's revenue growth it caused").

In short, it is not clear that Novartis's advertisements and sales draw an association between the Entresto trade dresses and Novartis. Secondary meaning requires that the consuming public come to associate the appearance of the drug with the manufacturer. *Inwood Lab'ys*, 456 U.S. at 851 n.11 ("To establish secondary meaning, a manufacturer must show that, in the minds of the public, the primary significance of a product feature or term is to identify the *source* of the product rather than the product itself." (emphasis added)). The evidence here does not identify an advertising campaign so "prevalent" that it justifies inferring secondary meaning. Nor did Novartis demonstrate that the sales of Entresto were motivated in any part by consumer association of the trade dresses with Novartis. The Court therefore finds that the first factor weighs in favor of MSN.

b. Length and exclusivity of use

For about ten years, Novartis has exclusively sold pills featuring the trade dresses of Entresto in the heart failure medication market. D.E. 4-5 ("Ward Decl.") ¶ 8. *Duraco* raised the specter of "seriously transgressing the protective zones mapped by the patent laws" in finding that trade dress protects a product configuration when there has been no showing of secondary meaning. 40 F.3d at 1450-51. The Third Circuit there explained that "*any* perceptible product feature or combination or arrangement of features *can* distinguish goods, and perhaps is likely to do so if, as a rule, nobody else were allowed to copy it." *Id.* at 1447; *see also id.* at 1450 n.12 ("In the design protection area, our construction of the Lanham Act is informed to some degree by the concurrent existence of the patent laws.") (citing *Digital Equip. Corp. v. Desktop Direct, Inc.*, 511 U.S. 863, 879 (1994)).

The Court is therefore wary of giving this factor too much weight here. Accordingly, this factor weighs in Novartis's favor, but not strongly. *See Buzz Bees Toys*, 20 F. Supp. 3d at 501

("five years, not so long a time as to raise a strong inference of consumer association with a single source" for product configuration trade dress (quoting *Duraco*, 40 F.3d at 1454)); *cf. McNeil Nutritionals, LLC v. Heartland Sweeteners LLC*, 566 F. Supp. 2d at 392 (finding that six years of exclusive use supported secondary meaning for a product labeling trade dress case, which "differs dramatically from trademark and product packaging") (quoting *Duraco*, 40 F.3d at 1452-53).

c. Copying

In the context of product configurations, attempts to copy "will quite often not be probative: the copier may very well be exploiting a particularly desirable feature, rather than seeking to confuse consumers as to the source of the product." *Buzz Bees Toys*, 20 F. Supp at 502 (quoting *Duraco*, 40 F.3d at 1453) (internal quotations omitted). Here, MSN states that it has mirrored the appearance of Entresto to provide its consumers with the functional benefits described above, *supra* section V.A.1. Novartis has submitted no evidence to the contrary. Without any indication that MSN is attempting to confuse consumers or pass off its tablets as Novartis's, MSN's copying is not probative of secondary meaning. Therefore, this factor weighs in favor of MSN or is neutral.

d. Customer surveys and testimony

Novartis provides no direct evidence demonstrating that consumers have come to associate the colors, size, and shape of Entresto with Novartis. While Novartis's expert states that she was "able to recognize Entresto just by seeing the pills," Nayeri Decl. ¶ 20, this evidence is not enough. As an initial matter, a single declaration does not show that the Entresto trade dresses achieved secondary meaning in the minds of the consuming public. 2 J. THOMAS MCCARTHY, MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION § 15:45 (5th ed.). But more importantly, the declaration does not show that Novartis's expert specifically associated the Entresto trade dresses with *Novartis itself*. Novartis offers no other evidence of customer surveys or testimony.

Although, customer surveys and testimony are not required to demonstrate secondary meaning *Cococare Prods.*, 538 F.3d at 201, their absence is significant here where Novartis offers little to support its arguments that the consuming public has come to associate the mere appearance of Entresto tablets with Novartis.

e. Use of trade dress in trade journals and media

Extensive use of a trade dress in trade journals and media can support a finding of secondary meaning. *Tyson Foods*, 863 F.3d at 231. The publications that Novartis points to, however, suffer from a similar infirmity as Novartis's advertisements. The issue here is the color, size, and shape of Entresto and the association of those features collectively with *Novartis as a brand*. Some of the publications that Novartis relies upon do not even include images of Entresto or if they do, include images of only one dosage strength.[13] *See, e.g.*, PI Mot. at 22 (citing D.Es. 4-21, 4-22, 4-36). This does not help Novartis. *Truinject Corp. v. Galderma S.A.*, 694 F. Supp. 3d 491, 508-09 (D. Del. 2023) (finding insufficient evidence of trade dress in part because "only a fraction of the Instagram posts and journal articles actually included the trade dress"). While some of the other exhibits do include an image of all three dosage strengths, D.Es. 4-23, 4-26, 4-30, these few publications do not persuade the Court that the consuming public has come to associate small oval violet white, pale yellow, and light pink tablets with Novartis as a brand. This factor weighs in favor of MSN.

[13] Novartis does not explain how an image of the Target Dose (light pink tablet) causes a consumer to associate the other color (violet white and pale yellow) tablets with Novartis. Nor does Novartis explain how the features of the Entresto trade dress, i.e., color, shape, and size, come to signify Novartis based upon images that do not reliably indicate size.

f. Company size and number of sales

Novartis is a well-known global company within the pharmaceutical industry with net sales exceeding $45.4 billion. Miller Decl. ¶ 6. Entresto is the top-selling heart failure medication and is responsible for over $10.5 billion in sales to approximately over 2.5 million patients. Miller Decl. ¶¶ 20, 25-26. There is no doubt that Novartis as a company and Entresto as a product are highly successful. These factors weigh in favor of Novartis.

g. Weighing the secondary meaning factors

The secondary meaning factors present a complex case here. Novartis asks this Court to conclude that consumers have come to associate the appearance of Entresto—small ovaloid violet white, pale yellow, and light pink tablets—with Novartis. There is evidence that the consuming public has come to associate the overall appearance of the drug products with the *drug product's ingredients and/or effects*, but that answers a question distinct from whether the consuming public has come to associate the tablets' overall appearance with *Novartis as the source*. On the one hand, Entresto is a highly successful product, it has been the only heart medication with its particular appearance for the past decade, and Novartis is a well-known company in the pharmaceutical industry. On the other hand, Novartis has provided no direct evidence of consumer association, media publications feature the appearance of Entresto only a fraction of the time, and Novartis has not emphasized the size, shape, and color of Entresto in its advertisements or linked those features to Novartis itself.[14] On these facts—and considering the Supreme Court's and Third Circuit's warnings against overextending trade dress protection—the Court finds it difficult to infer that like the "Purple Pill" for Astrazeneca and the red outsoles for Christian Louboutin shoes, small oval

[14] The advertisements that Novartis submitted as exhibits do not appear to even mention Novartis. *See supra* section V.A.2.a.

off-white and pastel tablets have achieved secondary meaning in the minds of the consuming public.

3. Likelihood of Confusion

To obtain trade dress protection, Novartis must also show a likelihood of confusion. To satisfy this element of trade dress infringement, Novartis must show "that an appreciable number of ordinarily prudent consumers of the type of product in question are likely to be confused as to the source of the goods." *Versa*, 50 F.3d at 200. "The mere possibility that a consumer might be mislead is not enough." *Id.* (quoting *Surgical Supply Serv., Inc. v. Adler*, 321 F.2d 536, 539 (3d Cir. 1963)). Typically, courts in the Third Circuit review the following factors to analyze likelihood of confusion:

> (1) the degree of similarity between the owner's mark and the alleged infringing mark; (2) the strength of the owner's mark; (3) the price of the goods and other factors indicative of the care and attention expected of consumers when making a purchase; (4) the length of time the defendant has used the mark without evidence of actual confusion arising; (5) the intent of the defendant in adopting the mark; (6) the evidence of actual confusion; (7) whether the goods, [even if not] competing, are marketed through the same channels of trade and advertised through the same media; (8) the extent to which the targets of the parties' sales efforts are the same; (9) the relationship of the goods in the minds of consumers because of the similarity of function; (10) other facts suggesting that the consuming public might expect the prior owner to manufacture a product in the defendant's market, or that he is unlikely to expand into that market.

Interpace Corp. v. Lapp, Inc., 721 F.2d 460, 463 (3d Cir. 1983) ("*Lapp* factors").

Product configuration cases are subject to a somewhat different approach here too. In *Versa*, the Third Circuit reasoned that because "product configurations are not reliable as source indicators" and because "substantially identical products are often sold by different manufacturers under different names, consumers are accustomed to relying on product packaging and trademarks to identify product sources." *Versa*, 50 F.3d at 201. As a result, consumers tend to "look to the packaging, trademarks, and advertising used to market the product" as an indicator of the product's

source. *Id.* at 202-03. Therefore, in product configuration cases, although courts should assess all *Lapp* factors, they should give most weight to the product's labeling,[15] packaging, and advertisements in assessing likelihood of confusion. *Id.*

The Third Circuit's reasoning in *Versa* applies in equal force to the prescription drug context. *First*, as explained above, this is a product configuration trade dress case, *see supra* section V.A.2. *Second*, the prescription drug industry is also one where substantially similar drug products are often sold by different manufacturers. *See Versa*, 50 F.3d at 201, 203; *see also* Nithiyandam Decl. ¶ 12; Clark Decl. ¶¶ 83-84, D.E. 13-23. *Third*, consumers exercise increased care, and this industry is one where the ultimate patient is "not necessarily involved in the decision to select one drug over another." *Astrazeneca*, 145 F. Supp. 3d at 317; *see also* D.E. 13-49 ("Ardehali Decl.") ¶¶ 27, 35-39; Shimer ¶ 48. Accordingly, although the Court analyzes all relevant *Lapp* factors, it assigns most weight to differences in advertising, packaging, and labeling.

a. Degree of similarity

As this Court found before, MSN's tablets look "strikingly similar" to Entresto. PI Opinion at 13. Trademark cases are typically "open and shut" when a defendant competitor uses an identical mark. *Opticians Ass'n of Am. v. Ind. Opticians of Am.*, 920 F.2d 187, 195 (3d Cir. 1990) (quoting 2 J. THOMAS MCCARTHY, MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION, § 23:7 (2d ed. 1984)). But because appearance tends not to be a reliable source indicator, "a finding of substantial similarity of trade dress in a product configuration does not by itself strongly suggest a likelihood of confusion." *Versa*, 50 F.3d at 201-02. This factor therefore weighs in favor of Novartis but not significantly.

[15] The Third Circuit refers to the "container, package, wrapper, or label of the manufacturer's or trader's name" here. *Versa*, 50 F.3d at 203. The Third Circuit was not referring to a drug's Highlights of Prescribing Information, which is commonly referred to as a drug's "label."

b. Strength of the owner's mark

In a product configuration case, evidence must indicate "actual *reliance* by consumers on a particular product configuration as a source indicator before crediting that configuration's 'strength' toward likelihood of confusion." *Versa*, 50 F.3d at 203; *see also Wal-Mart*, 529 U.S. at 213 ("In the case of product design, as in the case of color, we think consumer predisposition to equate the feature with the source does not exist."). Here, there is no evidence that healthcare providers or patients rely on size, shape, and color to identify the manufacturing source of the tablets or that product appearance plays a role in consumers' selection processes. *See Versa*, 50 F.3d at 204. At most, there is evidence that a healthcare provider was able to identify Entresto by simply seeing the tablets but that does not suffice. *See supra* section V.A.2.d. Therefore, this factor weighs in favor of MSN.

c. Consumer care in purchase

i. Exercise of care

In the product configuration context, "one expects a consumer exercising ordinary care to ascertain the source of a product to rely much more on packaging, trademarks, and adverting, which if not deceptive tend to reveal the product's source unambiguously, than on the product configuration . . . ." *Versa*, 50 F.3d at 204 (finding that reliance on a product's configuration as a source identifier would be rare). The parties here do not discuss the packaging of the drug products. However, the exhibits Novartis submitted demonstrate that drug containers are clearly labeled with the Entresto trademark. *See, e.g.*, D.E. 4-30. And Novartis does not argue that MSN's proposed packaging is deceptive. Without any evidence that consumers would be confused about the drug product's source based upon its packaging, this tips in favor of MSN.

With respect to trademarks, this Court previously found that there was no likelihood of confusion between the trademarks Novartis and Novadoz. PI Opinion at 18-21. Accordingly, the Court finds that this tips in favor of MSN too. Finally, the Court notes that while the record does not identify any MSN advertisements, Novartis's own advertisements do consistently use the Entresto trademark as well. Novartis's use of Entresto in its advertisements tips in favor of MSN too.

ii. Consumer care

The Third Circuit has directed courts to heavily weigh a consumer's degree of care in product configuration cases. *See Versa*, 50 F.3d at 204 ("We believe that this factor takes on enhanced importance when a claim is made for infringement of trade dress in a product configuration [case]."). The Court also notes that healthcare providers are sophisticated and familiar with the drug industry. *Checkpoint Sys.*, 269 F.3d at 286. To the extent that patients should be considered, they tend to exercise a greater degree of care when it comes to costly medical products, even though they are not as sophisticated as healthcare providers. *See McNeil Nutritionals*, 511 F.3d at 365. And the more sophisticated consumers are and the greater the care they exhibit, the less the likelihood of confusion. *Checkpoint Sys.*, 269 F.3d at 284 (citing *Versa*, 50 F.3d at 204).

The Third Circuit has cautioned courts against placing too much weight on the consumer care in the context of pharmaceuticals. *See Kos Pharms.*, 369 F.3d at 716 (collecting cases justifying a stricter standard in the medical context to prevent a likelihood of confusion). The Third Circuit's admonition, however, came in the context of a trademark case where two drugs treated the same conditions and had similar sounding names, but had different active ingredients. *Kos Pharms.*, 369 F.3d at 716-17. Here, however, Novartis's drug and MSN's drug would have

the same active ingredients, would be bioequivalent, and healthcare providers would not rely on the disputed trade dress to issue prescriptions. Nithiyanadam Decl. ¶¶ 3-5; Ardehali Decl. ¶¶ 29-30. Therefore, this factor slightly weighs in MSN's favor or is neutral.

d. Actual confusion and lack thereof

Because MSN's generic is not yet on the market, the fourth and sixth *Lapp* factors, which relate to actual confusion, cannot be analyzed. These factors therefore favor neither party.

e. Intent to infringe

"Evidence of intentional, willful and admitted adoption of a mark closely similar to the existing mark weighs strongly in favor of finding a likelihood of confusion." *Kos Pharms.*, 369 F.3d at 721 (quoting *Checkpoint*, 269 F.3d at 286) (internal quotations omitted). However, copying does not alone establish secondary meaning, *American Beverage Corp. v. Diageo North America, Inc.*, 936 F. Supp. 2d 555, 602 (W.D. Pa. 2013), and in product configuration cases, is often not probative, *Duraco*, 40 F.3d at 1453. Here, MSN submits evidence demonstrating that it sought to mimic the trade dress of Entresto for functional reasons. Clark Decl. ¶ 53; Nithiyandam Decl. ¶¶ 8, 13-14; Shimer Decl. ¶¶ 27-47. Novartis submits no evidence that MSN intends to pass off its generic tablets as Novartis's. Therefore, this factor is neutral or weighs in MSN's favor.

f. Factors 7-10

Although MSN seeks to enter the market as a generic, it will compete for the same consumers as Novartis. *Astrazeneca AB*, 145 F. Supp. at 318. Therefore, these factors weigh in favor of Novartis too.

g. Weighing the Lapp factors

The Court finds that there is not a likelihood of confusion here between Novartis and MSN based upon the trade dresses here. In the ordinary trademark case, substantial similarity and

competition in the same market would suffice. This is not such a case. As best as the Court can discern, the advertisements and packaging surrounding Novartis's product—which consumers are more likely to look to for source identification—clearly label it as Entresto. Novartis's trade dress is weak, and it has not shown that MSN mimicked Entresto to cause confusion. And generics regularly mimic the product configurations of branded counterparts. *See supra* section V.A.1.b. In this context, the factors in MSN's favor outweigh the tablets' similarity and participation in the same market, or at least make likelihood of confusion a close call.

Having concluded that the size, color, and shape of Entresto are functional, have not acquired secondary meaning, and are not subject to a likelihood of confusion, the Court finds that Novartis is not likely to succeed on the merits of its trade dress infringement claim.

B. Irreparable Harm[16]

A preliminary injunction should not issue "unless the moving party shows that it specifically and personally risks irreparable harm." *Liberty Lincoln-Mercury, Inc. v. Ford Motor Co.*, 562 F.3d 553, 557 (3d Cir. 2009). Injuries fully compensable by monetary damages are not irreparable. *Id.* "[L]oss of control of reputation, loss of trade, and loss of will," however, cannot be redressed solely by monetary damages and may therefore justify injunctive relief as a remedy. *Kos Pharm.*, 369 F.3d at 726.

In a trademark infringement case, when a plaintiff demonstrates a likelihood of success on the merits, the plaintiff is entitled to a rebuttal presumption of irreparable harm. *Nichino*, 44 F.4th at 184-85. However, when the plaintiff has failed to show a likelihood of success on the merits,

[16] The Court need not reach the other preliminary injunction factors because "[a] plaintiff's failure to establish any element in its favor renders a preliminary injunction inappropriate." *Nichino Am., Inc. v. Valent U.S.A. LLC*, 44 F.4th 180, 185-86 (3d Cir. 2022) (quoting *NutraSweet Co. v. Vit-Mar Enters., Inc.*, 176 F.3d 151, 153 (3d Cir. 1999)). However, for the sake of completeness, the Court will address the remaining prongs required for a preliminary injunction.

the presumption does not apply, and plaintiff must independently show it "specifically and personally risks irreparable harm." *Liberty Lincoln-Mercury*, 562 F.3d at 557; *see also Nichino*, 44 F.4th at 184 (affirming the district court's denial of a preliminary injunction because "Valent rebutted the presumption, and Nichino did not independently show irreparable harm"). Because Novartis has not shown a likelihood of success on its trade dress infringement claim, the Court addresses the merits of Novartis's irreparable harm theories without applying the presumption outlined in *Nichino*.

Novartis's concerns are predominantly grounded in its fear that MSN's generic may turn out to be defective and may thereby harm Novartis's reputation. PI Mot. at 37-38. *First*, Novartis worries that because MSN's drug label omits certain dosing information, Novartis's reputation will bear the blame when healthcare providers prescribe the wrong dose of Entresto after consulting MSN's drug label after being led astray by images of MSN's generic. As an initial matter, Novartis's expert declarations do not contend that this hypothetical chain of events is likely to occur—they contend only that it *could*. *See* Ward Decl. ¶ 20 (certain patients *could* receive a higher dose than is directed by the Entresto label") (emphasis added), ¶ 21 ("A patient . . . *could* believe the MSN Generic is Entresto . . . .") (emphasis added); Nayeri Decl. ¶ 29 ("An HCP *could* inadvertently mix up two drugs based on their appearance . . . . Exposure to that information *could* lead HCPs to consult the generic's FDA-approved label and packaging insert . . . . HCP confusion—and the inadvertent reference to the generic's prescribing information, rather than Entresto's prescribing information—*could* lead to patient harm. A confused HCP *might* fail to prescribe a reduced dosing regimen . . . .") (emphases added); *cf.* Ardehali Decl. ¶¶ 29-30 (disagreeing that "the appearance of tablets for an approved generic version of Entresto would

result in any kind of confusion or medical error among doctors based on the physical attributes of the drugs").

Moreover, the FDA and another court have already rejected Novartis's safety concerns based on MSN's proposed label. *Novartis Pharms. Corp. v. Becerra*, No. 24-2234, 2024 WL 3823270, at *6 (D.D.C. Aug. 13, 2024) (crediting the FDA's "unambiguous" judgment that the dosing information omitted from MSN's label "would *not* render [MSN's] drugs less safe or effective" and finding that Novartis's theory of harm requires "irrational[l]" behavior); *see also United Therapeutics Corp. v. Liquidia Techs., Inc.*, 74 F.4th 1360, 1369 (Fed. Cir. 2023) (collecting cases declining to disturb the FDA's judgment on questions of safety and efficacy).

Second, Novartis fears that MSN's generic may face contamination issues because it will be manufactured in countries where other drugs have faced quality control problems. Nayeri Rebuttal Decl. ¶ 10. But Novartis must show it specifically and personally risks irreparable harm. *Liberty Lincoln-Mercury*, 562 F.3d at 557. It does not suffice here for Novartis to argue that harm *may* befall MSN and that consumers *may* blame Novartis for it.

Third, Novartis fears that illegal substitution may occur or that confused patients will accidentally request refills of MSN's generic instead of refills of Entresto. PI Mot. at 38. But again, Novartis provides no evidence that illegal substitution is likely to occur. *See Shire*, 329 F.3d at 35-56 (distinguishing trademark cases relating to prescription drugs in part because "there was evidence of the passing off of the defendant's product"). Moreover, patients are notified when their drugs are swapped for a generic. *See, e.g.*, *Becerra*, 2024 WL 3223270, at *7. The Court therefore does not credit these theories of irreparable harm either.

Finally, Novartis's remaining fears of lost sales are economic in nature and compensable by damages. Indeed, courts in this district and others regularly find that lost sales are compensable.

See, e.g., *Otsuka Pharm. Co., Ltd. v. Torrent Pharms., Ltd., Inc.*, 99 F. Supp. 3d 461, 501 (D.N.J. 2015) (collecting cases). Accordingly, Novartis's injuries, as articulated, do not warrant the extraordinary remedy of injunctive relief.

C. Balance of Harms

The third prong of the preliminary injunction analysis requires the Court to "balance the relative harm to the parties, *i.e.*, the potential injury to the plaintiff if an injunction does not issue versus the potential injury to the defendant if the injunction is issued." *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharms. Co.*, 290 F.3d 578, 596 (3d Cir. 2002). Here, MSN would lose its first-mover advantage, potentially to Noratech, if MSN is barred from entering the market. D.E. 13-2 at ¶¶ 30-32. Such injury would impose significant hardship on MSN.

Novartis claims it will lose goodwill, but those injuries are speculative. But even if the Court credited Novartis's theories of reputational harm, its harm would be outweighed by the harm to MSN. *See In re Entresto (Sacubitril/Valsartan) Patent Litig.*, No. 20-md-2930, 2024 WL 3757086, at *5 (D. Del. Aug. 12, 2024). Therefore, the balance of harms favors MSN.

D. Public Interest

Novartis's exclusivity over Entresto may not continue indefinitely. While protection of its trade dress would nevertheless permit generic counterparts to enter the market using different colors and/or shapes, those differences would come at the expense of patient's expected visual continuity and would impact patient adherence. The Lanham Act encourages competition. *See Shire*, 329 F.3d at 353. It is not a backstop to loss of exclusivity or a tool to extend and entrench market dominance after a patent's expiration. *See Versa*, 50 F.3d at 204 ("The penumbra of the federal patent laws restricts the degree to which courts may grant legal recognition of consumer reliance on product configurations as source indicators . . . ."). There is little question here that

denial of injunctive relief and the availability of a generic alternative to a life-saving medication is in the public interest.

VI. CONCLUSION

Having determined that none of the preliminary injunction factors favor Novartis, the Court will **DENY** Novartis's Motion for a Preliminary Injunction and will **DENY** Novartis's Motion for an Injunction Pending Appeal. An appropriate Order accompanies this Opinion.

Dated: July 15, 2025

Evelyn Padin, U.S.D.J.